

DT07 Rec'd PET/PTO 25 JUN 2004

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Practitioner's Docket No. 61535 (46342)

CHAPTER II

**TRANSMITTAL LETTER
TO THE UNITED STATES ELECTED OFFICE (EO/US)
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)**

PCT/JP02/13782 27 December 2002 28 December 2001
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED

METHOD OF QUANTIFYING NUCLEIC ACID AND KIT FOR QUANTIFYING NUCLEIC ACID
TITLE OF INVENTION

Makoto KOBAYASHI, Toshimitsu ARAI, Fumika MATSUMURA
APPLICANTS

**Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
ATTENTION: EO/US**

NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

WARNING: Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing - See 37 C.F.R. § 1.8.

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111. 37 C.F.R. § 1.494(f).

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date, June 2004, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EV438969753US, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, MAIL STOP PCT.

Michelle P. Chicos
(type or print name of person mailing paper)

Signature of Michelle P. Chicos 00000002 041105 10500050

Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

* Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

* "Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of the requirement that a mailing label be placed on the petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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14. [X] Additional documents:
- a. [X] Copy of request (PCT/RO/101)
 - b. [X] International Publication No. WO 03/057880 A1
 - i. [] Specification, claims and drawing
 - ii. [X] Front page only
 - c. [X] Preliminary amendment (37 C.F.R. § 1.121)
 - d. [X] Other: Copy of

PCT/IPEA/416
PCT-EASY Version 2.92
Form PCT/IB/304
Form PCT/ISA/220
Sequence Listing (paper copy and 3 1/2 inch
Diskette containing same)
Sequence Listing Transmittal

15. [X] The above checked items are being transmitted
- a. [X] before 30 months from any claimed priority date.
 - b. [] after 30 months.

16. [] Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on _____, namely:
- _____
- _____

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).*

NOTE: *"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).*

[X] The Commissioner is hereby authorized to charge the following additional fees that may be required or credit any excess fee paid by this paper and during the entire pendency of this application to Account No. **04-1105**.

[X] 37 C.F.R. 1.492(a)(1), (2), (3), and (4) (filing fees)

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- b. ☒ is submitted herewith, and such oath or declaration
- i. ☒ is attached to the application.
- ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. 1.70.
- iii. ☐ will follow.

Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):
- a. ☒ is transmitted herewith.
- b. ☐ has been transmitted by the International Bureau.
Date of mailing (from form PCT/IB/308): .
- c. ☐ is not required, as the application was searched by the United States International Searching Authority.
- d. ☐ will be transmitted promptly upon request.
- e. ☐ has been submitted by applicant on _____.
Date

12. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98:
- a. ☒ is transmitted herewith.
Also transmitted herewith is/are:
☒ Form PTO-1449 (PTO/SB/08A and 08B).
☒ Copies of citations listed.
- b. ☐ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).
- c. ☐ was previously submitted by applicant on _____.
Date

13. ☒ An assignment document is transmitted herewith for recording.

A separate ☒ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

TAKEDA CHEMICAL INDUSTRIES, LTD.
1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi
Osaka 541-0045 JAPAN

THIS RECEIPT PCT/PTO 25 JUN 2004

5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. 371(c)(3)):

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NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

- a. ☐ are transmitted herewith.
b. ☐ have been transmitted
i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/IB/308): _____
ii. ☐ by applicant on _____.
Date
c. ☒ have not been transmitted as
i. ☒ applicant chose not to make amendments under PCT Article 19.
Date of mailing of Search Report (from form PCT/ISA/210):
ii. ☐ the time limit for the submission of amendments has not yet expired.
The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.
6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):
a. ☐ is transmitted herewith.
b. ☐ is not required as the amendments were made in the English language.
c. ☒ has not been transmitted for reasons indicated at point 5(c) above.
7. ☒ A copy of the international examination report (PCT/IPEA/409)
☒ is transmitted herewith.
☐ is not required as the application was filed with the United States Receiving Office.
8. ☒ Annex(es) to the international preliminary examination report
a. ☒ is/are transmitted herewith.
b. ☐ is/are not required as the application was filed with the United States Receiving Office.
9. ☒ A translation of the annexes to the international preliminary examination report
a. ☒ is transmitted herewith.
b. ☐ is not required as the annexes are in the English language.
10. ☒ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115
a. ☐ was previously submitted by applicant on _____.
Date

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- i. ☒ A check in the amount of \$1,920.00 to cover the above fees is enclosed.
 ii. ☐ Please charge Account No. _____ in the amount of \$ _____.
 A duplicate copy of this sheet is enclosed.

****WARNING:** "To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).

WARNING: If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.

3. ☒ A copy of the International application as filed (35 U.S.C. 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

- a. ☐ is transmitted herewith.
 b. ☐ is not required, as the application was filed with the United States Receiving Office.
 c. ☒ has been transmitted
 i. ☒ by the International Bureau.
 Date of mailing of the application (from form PCT/IB/308):
 ii. ☐ by applicant on _____
 Date

4. ☒ A translation of the International application into the English language (35 U.S.C. 371(c)(2)):
 a. ☒ is transmitted herewith.
 b. ☐ is not required as the application was filed in English.
 c. ☐ was previously transmitted by applicant on _____
 Date
 d. ☐ will follow.

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1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

- a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).
- b. ☒ The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
[]*	TOTAL CLAIMS	50 - 20 =	30	x \$ 18.00 =	\$540.00
	INDEPENDENT CLAIMS	3 - 3 =	0	x \$ 86.00 =	\$0
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$290.00				\$290.00
BASIC FEE**	<input type="checkbox"/> U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: <input type="checkbox"/> and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(2) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 CFR 1.492(a)(4)) \$100.00 <input type="checkbox"/> and the above requirements are not met (37 CFR 1.492(a)(1)) \$720.00				\$920.00
	<input checked="" type="checkbox"/> U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the USPTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: <input type="checkbox"/> has been paid (37 CFR 1.492(a)(2)) \$750.00 <input type="checkbox"/> has not been paid (37 CFR 1.492(a)(3)) \$1060.00 <input checked="" type="checkbox"/> where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 CFR 1.492(a)(5)) \$920.00				
SMALL ENTITY	Total of above Calculations				= \$1,750.00
	Reduction by ½ for filing by small entity, if applicable. Affidavit must be filed. (note 37 CFR 1.9, 1.27, 1.28)				- \$
	Late fee of \$130.00 for filing oath or declaration after 30 months from filing date (37 C.F.R. § 1.492(e))				\$130.00
	Subtotal				\$1,880.00
	Total National Fee				\$1,880.00
	Fee for recording the enclosed assignment document \$40.00 (37 CFR 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				\$40.00
TOTAL	Total Fees enclosed				\$1,920.00

WARNING: Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.492(d)) results in abandonment of the application, it would be best to always check the above box. **500050**

☒ 37 C.F.R. 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. 1.17 (application processing fees)

☒ 37 C.F.R. 1.17(a)(1)-(5)(extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).


SIGNATURE OF PRACTITIONER

Reg. No.: 48,399

John B. Alexander
(type or print name of practitioner)

Tel. No.: (617) 439-4444

EDWARDS & ANGELL, LLP
P.O. Box 55874
P.O. Address

Customer No.: 21874

Boston, MA 02205

BOS2_449445.1

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Docket No. 61535 (46342)

DT09 Rec'd PCT/PTO 25 JUN 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Makoto KOBAYASHI et al.

Serial No.: Not Yet Assigned

Group No.: Not Yet Assigned

Filed: June 25, 2004

Examiner: Not Yet Assigned

[Express Mail No. EV438969753US]

For: METHOD OF QUANTIFYING NUCLEIC ACID AND KIT FOR
QUANTIFYING NUCLEIC ACID

Mail Stop PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY,
AND/OR AMENDMENT PERTAINING THERETO
FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE
AND/OR AMINO ACID SEQUENCE

(check and complete this item, if applicable)

1. ☐ This replies to the Office Letter DATED _____.

NOTE: *If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the application number from the return post card or the attorney's docket number added.*

☐ A copy of the Office Letter is enclosed.

IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, John B. Alexander

(type or print name of person signing below)

state the following:

ITEMS BEING SUBMITTED

3. Submitted herewith is/are:

(check each item as applicable)

A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application.

(Submission-Nucleotide and/or Amino Acid Sequence--page 1 of 5)

Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. Section 1.821(c) and 37 C.F.R. Sections 1.822 and 1.823.

- B. ☐ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. Section 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. Sections 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. Section 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:
Application No.:
Filed:
For:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form
(other application)

"Sequence Identifier"
(this application)

NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. Section 1.821(e).

- E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. Section 1.821(g).
- ☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. Section 1.821(b).
- F. ☐ Because this submission is made in fulfilling the requirement under 37 C.F.R. Section 1.821(g), a statement that the submission includes no new matter.
- ☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. Section 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING"
AND COMPUTER READABLE COPY ARE THE SAME
AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:

(complete applicable item A and/or B)

- A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.
- B. ☒ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

STATUS

5. Applicant is

☐ a small entity.

☒ other than a small entity.

EXTENSION OF TERM

6.

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec.10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. Section 1.645 for extensions of time in interference proceedings and 37 C.F.R. Section 1.550(c) for extensions of time in reexamination proceedings.

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. Section 1.136 apply.

(complete (a) or (b) as applicable)

- (a) ☐ A applicant petitions for an extension of time under 37 C.F.R. Section 1.136 (fees: 37 C.F.R. Section 1.17(a)(1)-(4)) for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 400.00	\$ 200.00
<input type="checkbox"/> three months	\$ 920.00	\$ 460.00
<input type="checkbox"/> four months	\$1,440.00	\$ 720.00

Fee \$ _____

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured, and the fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

OR

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

FEE PAYMENT

8. ☐ Attached is a check in the sum of \$ _____.

- ☐ Charge Account No. _____ the sum of \$ _____.
A duplicate of this transmittal is attached.

FEE DEFICIENCY

9.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

10. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105 .

SIGNATURE(s)

John B. Alexander

(type or print name of person signing statement)


Signature

June 25, 2004
Date

EDWARDS & ANGELL, LLP

P.O. Box 55874

P.O. Address of Signatory

Boston, MA 02205

(If applicable)

Tel. No.: (617) 439-4444

Reg. No. 38,256

Customer No.: 21874

- ☐ Inventor
- ☐ Assignee of complete interest
- ☐ Person authorized to sign on behalf of assignee
- ☐ Practitioner of record
- ☐ Filed under Rule 34(a)
- ☒ Registration No. 48,399
- ☐ Other

(complete the following, if applicable)

(type name of assignee)

Address of assignee

Title of person authorized to sign on behalf of assignee

A "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" is attached.

Assignment recorded in PTO on _____

Reel _____ Frame _____